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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,587	05/16/2001	Yoshiki Sasai	00766.000044.	1416

5514 7590 01/22/2009  
FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER
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SGAGIAS, MAGDALENE K

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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01/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/855,587	<b>Applicant(s)</b> SASAI ET AL.	
	<b>Examiner</b> MAGDALENE K. SGAGIAS	<b>Art Unit</b> 1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 08 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1, 15, 18-21, 23-24, 72, 74-75, 80-87.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Anne-Marie Falk/  
 Anne-Marie Falk, Ph.D.  
 Primary Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue claims 1, 80 and 81 are amended more specifically to recite the subject matter of the present invention. Applicants argue claims 1, 15, 18-21, 23, 24, 72, 74, 75 and 80-87 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and for failing to enable one of ordinary skill to make and use the present invention. This rejection is explicitly made only in view of Applicants' Preliminary Amendment dated August 17, 2007 (Office Action, from page 3, last two lines to page 4, and first two lines). This is the sole issue remaining herein. Although that Preliminary Amendment was not intended to change the scope of the claims and was simply to present the claims in more idiomatic fashion, solely in order to reduce the issues and expedite prosecution herein, the claims are above amended to recite the language presented prior to the August 17, 2007 Preliminary Amendment. Accordingly, this rejection is now plainly overcome. In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition.

These arguments are not persuasive because Applicants amendment to the claims 1, 80 and 81 back to the same language as of 8/17/08 office action fail to overcome the issues of claim rejections-35 USC 112 first-written Description and enablement for the reasons of record (see non-final office action, mailed 10/4/07, pages 2-5). To emphasize the issue claims as amended Applicants have not provided literal support for these steps and what is accomplished by these steps cannot be found in the specification. Moreover, figurative support for these steps, wherein it results in "differentiation of an embryonic stem cell into a neural crest cell or a neural tube cell" cannot be found and appears to be inconsistent with the teachings of the present specification. More specifically, it appears the BMP-4 in the absence of retinoic acid is affecting the embryonic stem cell to differentiate preferentially into neural cell lineage. The method steps in examples 1 or 2 of the specification, wherein EB5 embryonic stem cells differentiate into neuronal cells expressing neural specific markers or into non-neuroectodermal cells respectively, so not support the production of a neural crest cell or a neural cell. Moreover, the method steps of example 14, wherein differentiation induction of embryonic stem cell into neural cells expressing the various neural markers as shown in Table 1 of example 14, do not support the production of a neural crest cell or a neural tube cell by way of the claimed methods. More specifically in example 14, EB5 cells were precluded for 4 days before the addition of BMP-4. It is noted that the Applicants fail to point to any specific support for the present claim amendments (see office action mailed 10/4/07).